

MEDICAL LABORATORY BOARD MINUTES

Date: April 15, 2004

Time: 9:00 a.m., CDT

Location: Cumberland Room
Ground Floor, Cordell Hull Building
425 Fifth Avenue North
Nashville, TN 37247

Members Present: Kelly S. Terry, Medical Technologist, Chairperson
Dennis Carter, MD
Jere Ferguson, MD
Edward McDonald, MD
Thomasa Cooper, Medical Technologist
Martha Duncan, Medical Technologist
Sharon Hargrove, Medical Technologist
Linda Lahr, Medical Technologist
Alison McDonald, Cytotechnologist
Monya Faye Pryor, Citizen Representative
Delores Voigt, MT Hospital Administrator

Members Absent: Charles R. Handorf, MD
Debbie Stinnett, Medical Technologist

Staff Present: Lynda S. England, Medical Technologist, Director
Cheryl H. Thacker, Medical Technologist, Consultant
Robbie Bell, Health Related Boards Director
Jerry Kosten, Rules Manager
Robert Kraemer, Jr., Advisory Attorney
Onezean Otey, Jr., Medical Technologist Consultant/Surveyor,
East Tennessee Regional Office
Sandra S. Bogard, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office
Irmgard Brown, Medical Technologist Consultant/Surveyor,
Middle Tennessee Regional Office

Staff Absent: Julia Daniels, Medical Technologist Consultant/ Surveyor
East Tennessee Regional Office
Mary Hamblen, Medical Technologist Consultant/Surveyor
West Tennessee Regional Office
Karon Daniels, Medical Technologist Consultant/ Surveyor,
West Tennessee Regional Office

Quorum:

A sufficient number of board members were present to constitute a quorum.

New Board Member Introduction/Reappointments:

Ms. Terry introduced Ms. Thomasa E. Cooper, MT to the full board and the audience. Ms Cooper was appointed to the Medical Technologist- Supervisor board position formerly held by Ms. Mary Anne Giannini.

Ms. Martha Duncan, MT was reappointed to a second term serving as Medical Laboratory Technologist-Supervisor board member.

Presiding Officer:

The meeting was called to order by Ms. Terry at 9:07 a.m. Board Members introduced themselves to the audience.

Board Minutes:

A motion to approve the January 15, 2004 full board minutes with the noted changes on page two, paragraph two was made by Ms. Duncan. A second to the motion was made by Ms. Lahr. The minutes were approved.

A motion to approve the Personnel & Education minutes from the January 14, 2004 meeting was made by Ms. Duncan. A second to the motion was made by Ms. Lahr. The minutes were approved.

Board Report-Personnel & Education Committee:

Linda Lahr, MT
Committee Chair

Ms. Lahr presented report of actions from the Personnel & Education Committee meeting held on April 14, 2004. A motion to accept this report was made by Dr. McDonald. A second to the motion was made by Dr. Ferguson. The motion carried and the Committee actions were approved.

Board Report-Tennessee Professional Peer Assistance Program:

Leanne Busby DSN, RNC-State Director

Ms. Busby made the report to the board concerning activities of the Tennessee Professional Peer Assistance Program relative to medical laboratory professionals.

There were two (2) individuals referred by the staff consultant to be evaluated by this advocacy program. The complete report is on file in administrative office. A motion to accept this report was made by Ms. Duncan, with a second to the motion by Dr. Ferguson. The motion carried.

The board discussed the renewal of the contract with Tennessee Professional Assistance Program. A motion to approve a new contract for a five (5) year period beginning in July 2004 was made by Dr. Ferguson. A second to the motion was made by Ms. Hargrove. The motion carried.

Board Report-Rules:

Jerry Kosten-Rules Manager

A. Rules Amendments:

Mr. Kosten reported on a rulemaking hearing held March 19, 2004 concerning the following amendments:

1. Rule 1200-6-1-.14, Rules for Medical Laboratory Personnel by requesting the student trainee permit be on-site with the trainee during clinical rotations authorizing clinical laboratory bench work under supervision.
2. Rule 1200-6-1-.20, Rules for Medical Laboratory Professionals regarding the review of all proficiency test reports by the director and staff.
3. Rule 1200-6-3-.07, Rules for Medical Laboratories correcting grammatical and/or incorrect citations to federal and state regulations.
4. Rule 1200-6-3-.08 Rules for Medical Laboratory Facilities pertaining to patient test management.
5. Rule 1200-6-3-.09 Rules for Medical Laboratory Facilities pertaining to test methodologies & equipment selections.

There were no comments presented to Mr. Kosten during the rulemaking hearing.

A roll call vote was taken with all members present saying aye.

The motion carried.

B. Authorize Rulemaking Hearing:

The board considered authorizing a rulemaking hearing for the following items:

1. Revise Rule 1200-6-1-.20(4) & Rule 1200-6-3-.14(6) pertaining to medical laboratory director on-site visits to the laboratory. No action was taken regarding this issue at this time.

2. The impact of the new CLIA Regulations on Rule 1200-6-3-.06. The new regulations became effective on January 12, 2004; however, surveyors are not writing deficiencies at this time. A Task Force was formed to study this matter.
3. Revision of Rule 1200-6-3.09(25)(a) pertaining to quality control in the clinical specialty of hematology. This change would encompass performing hematology quality control from the existing requirement of every eight (8) hours to every twenty-four (24) hours. A motion to authorize the rulemaking hearing was made by Dr. Ferguson with a second to the motion by Ms. Duncan. The motion carried.

Contested Case:

Daniel P. Walker
Medical Technologist-Supervisor
Nashville, TN
License#13028

This hearing has been continued until the July 2004 meeting.

Ratifications:

The following items were presented to the Board for ratification per staff, state surveyor or facility request:

- 1) Exemptions for point of care testing procedures (POCT) in a licensed facility (See Attachment 1).
- 2) Initial licenses for Clinical Laboratory Facilities (See Attachment 2).

Board Director's Report/Discussion:

Lynda S. England BS MT(ASCP)
Director

Ms. England reported several items to the Board members including administrative office statistics, contact with TNPAP for peer assistance services, upcoming Rulemaking hearings, newsletter project, legislative actions, investigations/consultants, website updates, 2004 Board meeting dates, and facility closures.

A motion to accept Ms. England's report was made by Ms. Duncan with a second to the motion by Ms. Hargrove. The motion carried.

Direct More Than Three (3) Labs
Rule 1200-6-3-.13(5) Medical Lab Facilities

John W. Templeton, M.D. was scheduled to appear before the board. Documentation was presented to the administrative office notifying the Department the fourth (4th) licensed laboratory he was to direct had reassigned the clinical specialty of arterial blood gases and pH to the main laboratory located in the same facility.

Dr. Templeton currently directs the following three (3) licensed facilities:
John W. Harton Regional Medical Center-Tullahoma, TN
Anatomic Pathology Laboratory of Winchester-Winchester, TN
Bedford County Medical Center-Shelbyville, TN.

No board action taken.

Reinstatement of License

There were no licenses reinstated during this meeting.

Reports/Discussion

Regional Consultant/Surveyor – Proficiency Testing (PT)
Complaints on Licensed Laboratory Facilities

A. East Tennessee Regional Office-Onezean Otey, Jr., Consultant I/Surveyor

Unsatisfactory or Unsuccessful Proficiency Testing:

There were four (4) self-reporting testing failures in which there were incorrect rulings based on clerical errors. All facilities submitted acceptable corrective action documentation.

Complaints:

The East Tennessee Regional Office had one (1) complaint of an unlicensed collection station. The complaint was substantiated and the paperwork is in process for licensure for this facility.

A motion to accept this report was made by Ms. Hargrove. A second to the motion was made by Cooper. The motion carried.

B. Middle Tennessee Regional Office- Sandra S. Bogard, Consultant II/Surveyor
Irmgard A. Brown, Consultant I/Surveyor

Unacceptable/Unsuccessful Proficiency Testing:

The number of licensed laboratories demonstrating a first occurrence of unsuccessful proficiency testing events (two out of three events) is one (1) with the analyte (1), CK-isoenzymes.

The number of State licensed laboratories with second (2nd) occurrence of unsuccessful proficiency testing events: none (0).

Complaints:

The Middle Tennessee Regional Office has conducted zero (0) complaint investigations January through March 2004.

A motion to accept this report was made by Ms. Hargrove with a second to the motion by Ms. Cooper. The motion carried.

B. West Tennessee Regional Office

Ms. England made the report in the absence of the regional surveyors.

Unacceptable/Unsuccessful Proficiency Testing:

The number of state licensed laboratories with a first occurrence of unsuccessful proficiency testing (two out of three or two in a row): two (2).

Facility #1: Analyte: Blood Gas, PO2.

Facility #2: Analyte Coagulation, Fibrinogen.

Both facilities returned an acceptable plan of correction with documentation of technical assistance.

The number of state licensed laboratories with second occurrence of unsuccessful proficiency testing (three out of four or three in a row): zero (0).

Complaint Investigations:

This report will be added to the July 2004 report document.

A motion to approve this report was made by Ms. Hargrove with a second to the motion by Ms. Cooper. The motion carried.

Health Related Board's Report/Discussion:

Robbie Bell, Director

Ms. Bell made a report on the disciplinary guidelines pertaining to all boards during this meeting.

A motion to accept this report was made by Dr. McDonald with a second to the motion by Ms. McDonald. The motion carried.

Office of General Counsel Report:

Robert J. Kraemer, Jr.
Advisory Attorney

Mr. Kraemer led the discussion of the following items:

1. **Dental Lab Director (03-1197)** The rulemaking hearing was held on October 1, 2003 and this amendment was adopted by the Board October 17, 2003, was sent to the Attorney General on October 21, 2003. It is still there.
2. **Disciplinary Rule (03-1311)** The rulemaking hearing was held on December 23, 2003 and this amendment was adopted by the Board on January 15, 2004, was sent to the Attorney General on January 27, 2004. It is still there.
2. **Temporary Permits and Cleanup (04-1037)** The rulemaking hearing was held on March 19, 2004 and after response to comments is ready for adoption at this meeting.

Litigation:

The Office of General Counsel currently has one (1) open disciplinary case pertaining to the Medical Laboratory Board.

A motion to accept this report was made by Dr. Ferguson with a second made by Ms. Lahr. The motion carried.

Bureau of Investigations (BIV) Report:

Lea Phelps
Disciplinary Coordinator

Ms. Phelps distributed the disciplinary report to the Board members, noting that the list comprised disciplinary actions on licensees beginning in July 1996 through November 2001.

A motion to accept this report was made by Dr. Carter with a second by Ms. Lahr. The motion carried.

Office of Health Licensure & Regulation:

Judy Eads, RN
Assistant Commissioner of Health

Ms. Eads did not make a report at this time.

Financial Report:

Lisa Tittle
Fiscal Officer

Ms. Tittle did not make a report at this time.

Waived Testing Procedures:

Additions/Deletions from- **1-Point of Care List**
 2-Health Fair/Health Screen List

A request was made for the addition of the clinical laboratory test for *Streptococcus Group A* to the waived test list for Point of Care testing. A motion to add *Streptococcus Group A* to the Point of Care waived test list was made by Ms. Duncan with a second made by Ms. Voigt. The motion carried.

A request was also made for the addition of the clinical laboratory test for calculated LDL cholesterol to the Point of Care testing list and the Health Fair/ Health Screen testing list. A motion was made to add the calculated LDL Cholesterol test to the Point of Care testing list and the Health Fair/ Health Screen testing list by Dr. Ferguson with a second made by Ms. Cooper. The motion carried.

Point of Care Task Force

This task force continues to meet but no inquiries were made to the board during this meeting.

Review Eligibility of Medical Laboratory Director

1. Aswani Yenamandra, Ph.D.-Nashville, TN – Director-Cytogenetics

Ms. Thacker informed the Board Dr. Yenamandra's file was complete and she has met the requirements for a Director of Cytogenetics. The applicant holds a Ph.D. degree in the clinical specialty of genetics and possesses a national boarding in clinical cytogenetics with the American Board of Medical Genetics. Ms. Hargrove motioned to approve this request for licensure. A second to the motion was made by Ms. Duncan. The motion carried.

2. Shahiedy I. Shahied, Ph.D.-Knoxville, TN-Director-Chemistry

Ms. Thacker informed the Board Dr. Shahied holds a Ph.D. in Physiology and Biochemistry and holds boarding by the American Board of Bioanalysis as a High Complexity Clinical Laboratory Director (HCLD). The laboratory Dr. Shahied intends to direct requires that the director possess national boarding as either a BCLD (Bioanalyst Clinical Laboratory Director) or a High Complexity Laboratory Director in the subspecialties of Microbiology and General Immunology. The Board informed Ms. Thacker that Dr. Shahied does not currently meet the qualifications for licensure in these areas and directed Ms. Thacker to send notification to

Dr. Shahied regarding the deficiencies. Upon satisfaction of the boarding requirements, Dr. Shahied's file will again be reviewed by the Board.

Statement of Next Meeting

The next meeting will be held on July 15, 2004 at 9 am, CDT in the Cumberland Room, Ground Floor Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010.

Record of Adjournment

With no further business to discuss, the meeting was adjourned at 3:30 p.m. on a motion properly presented by Ms. Duncan and seconded by Ms. Cooper. The motion carried.

Jere Ferguson, M.D.
Board Vice-Chairman

Date

Attachment 1
Medical Lab Board
Point of Care Exemption Requests
April 15, 2004

REQUEST FOR EXEMPTION-POINT OF CARE TESTING PROCEDURES

1. Erlanger Medical Center-East Campus
1775 Gunbarrel Road
Chattanooga, TN 37421-3185

Facility Representative: Mary Hooper
Laboratory Support Services Manager

This request was for Licensed Respiratory Therapists to perform and report sodium, potassium, chloride, CO₂, ionized calcium, glucose, hematocrit, BUN, creatinine, prothrombin/INR and lactate results in the medical center utilizing the i-STAT instrument and methodologies.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Hargrove. The motion carried.

2. Wellmont Health System Donor Services
Marsh Regional Blood Center
914 Broad Street
Kingsport, TN 37660

Facility Representative: Gail Price
Director of Laboratory Services

This facility request was for non-licensed personnel to test blood donor specimens for bacterial contamination in leuko-reduced platelet and pheresis products utilizing the Pall Bacterial Detection System (eBDS) in the donor center.

Dr. Ferguson and Ms. Lahr recused themselves from this vote. A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Hargrove. The motion carried.

3. Dynacare Tennessee
1924 Alcoa Highway
Knoxville, TN 37920

Facility Representative: Jacqueline Christie, MT (ASCP), CLSup
Point of Care Coordinator

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Medical Laboratory Board
Point of Care Exemption Requests
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This board reviewed the following requests:

- 1) Nursing Assistants to perform and report Rapid Strep testing procedures in the Residents Medicine Clinic (formerly the Faculty Internal Medicine Clinic) utilizing the Quick Vue Strep A Test Kit.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Pryor. The motion carried.

- 2) Licensed Nurses to perform and report lipid profiles and glucose testing procedures utilizing the Cholestech LDX Analyzer as part of the *4 Your Heart Program*, a program sponsored by the Center for Women's Health in the Heart, Lung, Vascular Institute at UTMCK.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Voigt. The motion carried.

- 3) CRNA's and Perfusionists to perform and report creatinine levels utilizing the i-STAT instrument in the Surgical Suites.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Dr. Ferguson. The motion carried.

- 4) Registered Nurses (RN's) to perform and report creatinine levels utilizing the i-STAT instrument in the Critical Care Areas, Heart Cath Lab and Special Procedures Unit of this facility.

A motion to approve this request was made by Dr. McDonald. A second to this motion was made by Dr. Ferguson. The motion carried.

4. LeBonheur Children's Medical Center
50 North Dunlap
Memphis, TN 38103

Facility Representative: Kathy Connelly
Point of Care Coordinator

Ms. Terry recused herself from this vote.

- 1) This request was for blood urea nitrogen (BUN), chloride and lactate analyses to be performed and reported by the following health professionals in the designated areas of this facility:

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Medical Laboratory Board
Point of Care Exemption Requests
April 15, 2004

- a. Certified Registered Nurse Anesthetists, Perfusionists & Registered Nurses in the Operating Room.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Voigt. The motion carried.

- b. Registered Nurses, Registered Respiratory Therapists & Certified Respiratory Therapists in the Intensive Care Unit (ICU), Extra Corporeal Membrane Oxygenation (ECMO) Unit.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Voigt. The motion carried.

- c. Registered Nurses, Registered Respiratory Therapists & Certified Respiratory Therapists on the Pediflite Transport.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Ms. Voigt. The motion carried.

- d. Registered Nurses, Registered Respiratory Therapists & Certified Respiratory Therapists in the Emergency Department.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Ms. Voigt. The motion carried.

2) This request was for Certified Nurse Anesthetists, Perfusionists & Registered Nurses to perform and report Clot Graphic/Thrombelastograph Testing on the Thrombelastograph (TEG) Coagulation Monitor in the Operating Room.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Dr. Ferguson. The motion carried.

- 5. Cleveland Community Hospital
2800 Westside Drive
Cleveland, TN 37312

Facility Representative: Stacy Allison, MT(ASCP)
Laboratory Manager

This facility request was for laboratory assistants to perform and report Lee-White Bleeding Times in this facility.

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Medical Laboratory Board
Point of Care Exemption Requests
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A motion to approve this request was made by Dr. Ferguson. A second to the motion was made by Ms. Pryor. The motion carried.

6. Gateway Health System
Gateway Medical Center
1771 Madison Street
Clarksville, TN 37043-3160

Facility Representative: Mary Bowles BSMT (ASCP), BSN RN
Point of Care Coordinator

This facility request was for the modification of a request approved October 1998:

- 1) Licensed nurses (RN's & LPN's), Nurse Practitioners, Physician Assistants & EMT-Paramedics to perform and report fecal occult blood testing in the Emergency Department & Occupational Health.
- 2) Licensed nurses (RN's & LPN's), Nurse Practitioners, Physician Assistants & EMT-Paramedics to perform and report urine dipstick testing in the L&D, ICN, Emergency Department & Occupational Health.
- 3) Medical Assistants perform and report fecal occult blood testing and urine dipstick testing procedures in the Occupational Health Department.

These tests are now on the Waived Test List Rule 1200-6-3-.17. There is no board exemption required to perform these clinical specialties.

Another exemption request was approved on July 2002 which granted in part:

- 1) Licensed nurses (RN's & LPN's), EMT-Paramedics to perform and report Strep A testing in the Emergency Department & Occupational Health.

This request is for Physician Assistants to perform and report Strep A testing procedures in the Emergency Department & Occupational Health.

A motion to approve this request was made by Dr. McDonald. A second to this motion was made by Dr. Ferguson. The motion carried.

- 2) Medical Assistants to perform and report Strep A testing in the Occupational Health Department.

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Medical Laboratory Board
Full Board
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A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Ferguson. The motion carried.

7. NorthCrest Medical Center
100 NorthCrest Drive
Springfield, TN 37172

Facility Representative: Glinda Jenkins, MT(ASCP)CLM
Laboratory Manager

This request was for:

- 1) Licensed Registered Nurses (RN's), Licensed Practical Nurses (LPN's) and Licensed Paramedics to perform and report Strep testing procedures in the Emergency Room utilizing the Q-Test Strep Kit.

Ms. Duncan recused herself from this vote.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Ms. Hargrove. The motion carried.

- 2) Licensed Registered Nurses (RN's), Licensed Practical Nurses (LPN's) and Licensed Paramedics to perform and report troponin I, myoglobin, CK-MB and BNP testing procedures in the Emergency Department utilizing the Biosite Triage System.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Ferguson. The motion carried.

8. Centennial Medical Center
2300 Patterson Street
Nashville, TN 37203

Facility Representative: Mary Wynn, MT(AMT)
Point of Care Coordinator

This request was for Registered Nurses (RN's) & Licensed Practical Nurses (LPN's) to perform and report Troponin and CK-MB in the Emergency Room.

Ms. Duncan and Ms. McDonald recused themselves from the discussion and vote.

Attachment 1
Medical Laboratory Board
Full Board
April 15, 2004

A motion to approve this request was made by Dr. McDonald with a second to the motion by Ms. Lahr. The motion carried.

9. Johnson City Medical Center
400 State of Franklin Road
Johnson City, TN 37604

Facility Representative: Karen Cox, MT
Point of Care Coordinator

Board members reviewed the following exemption requests:

- 1) Licensed Registered Nurses (RN's), Registered Respiratory Therapists, Paramedics & EMT personnel to perform and report sodium, potassium, chloride, BUN/urea, glucose, hematocrit, calculated hemoglobin, creatinine & troponin I testing procedures in the Emergency Department utilizing the i-STAT instrument and methodologies.

A motion to approve this request was made by Dr. McDonald with a second to the motion by Dr. Ferguson. The motion carried.

- 2) Certified Registered Nurse Anesthetists (CRNA's), & Licensed Registered Nurses (RN's) in the Same Day Surgery Center, to perform and report blood gases, ionized calcium, sodium, potassium, chloride, glucose, BUN/urea, hematocrit and calculated hemoglobin utilizing the i-STAT system in the Holding Area, Surgical Suites and Post Anesthesia Care Unit.

A motion to approve this request was made by Dr. McDonald. A second to the motion was made by Ms. Hargrove. The motion carried.

Attachment 2
Initial Facility Licenses
Medical Laboratory Board
April 15, 2004

INITIAL FACILITY LICENSES: REGIONAL SURVEYOR RECOMMENDATION

1. East Ridge Hospital Respiratory Care Department
941 Spring Creek Road
Chattanooga, TN 37421

Medical Laboratory Director: David H. Guan, M.D.
Pulmonology

Specialties: Arterial Blood Gases & pH

Surveyor: Julia Daniels, Consultant II/Surveyor
East TN Regional Office

Ms. Daniels was unable to attend this board meeting. Mr. Otey made the recommendation for licensure of this facility.

A motion to approve this request was made by Dr. Ferguson. A second to this motion was made by Ms Hargrove. The motion carried.

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